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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/424,091	02/23/00	KAY R	350013-66

HM22/0420

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EXAMINER	
DECLOUX, A	
ART UNIT	**PAPER NUMBER**
1644	6

DATE MAILED: 04/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/424,091	Kay
Examiner	**Art Unit**
DeCloux, Amy	1644

-- The MAILING DATE of this communication appears on the c v r sh et with th correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-20 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-20 are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

1. Applicant's submission of the instant application as a 371 is acknowledged, however the first claim does not provide a technical feature that is distinguished over the prior art, as evidenced by Wigzell et al. (WO-A-94 14067)(in IDS) who teach a method of identifying the V gene usage of T cells which are responsive in sarcoidosis patients. The method comprises obtaining bronchoalveolar samples from sarcoidosis patients (ie samples containing T cells which have responded to antigen) and samples from healthy subjects, and incubating the T cells with TCR specific monoclonal antibodies (with specificity for specific Valpha or Vbeta regions) and comparing the V gene usage of T cells in sick and healthy subjects (see entire article, including pages 47-62). Therefore, the instant invention lacks Unity of Invention.

2. This application contains claims directed to more than one embodiment of the generic invention. These embodiments are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

3. Therefore, applicant is required under 35 U.S.C. 121 and 372:

To elect a **specific embodiment**: of the method of identifying an antigen-responsive T cell comprising either A) for each of a plurality of T cell receptors or B) individually for each of a plurality of subsets of T cell receptors, as recited in claim 1, part 2.

To elect a **specific embodiment**: of the method of identifying an antigen-responsive T cell comprising either A) wherein a sample is obtained from a non-diseased site of an individual and from a diseased site of an individual, as recited in claim 4 or B) wherein a sample is obtained from a non-diseased individual and from a diseased individual, as recited in claim 5.

To elect a **specific embodiment**: of the method of identifying an antigen-

responsive T cell wherein the subset of T cell receptors is a subset wherein A) each T cell receptor comprises a specific alpha region as recited in claim 6, or B)) each T cell receptor comprises a specific beta region as recited in claim 7, or C) each T cell receptor comprises a specific alpha region and a specific beta region as recited in claim 8.

To elect a **specific embodiment**: of the method of identifying an antigen-responsive T cell wherein the method comprises a method which quantitates the amount of specific T cell receptor RNA or the amount of T cell receptor RNA in a specific subset, as recited in claims 2-11, or B) antibodies which bind to a specific T cell receptor or a specific subset of T cell receptors as recited in claims 12-14, or C) a method which quantitates the amount of specific T cell receptor DNA or the amount of T cell receptor DNA in a specific subset as recited in claims 15-17.

To elect a **specific embodiment**: of the method of treating a patient with an antigen mediated disease wherein the method comprises) T cell vaccination, B) anti-TCR antibody treatment or C)peptide immunization as recited in claim 20.

4. The species are distinct each from the other for the following reasons:

a. Methods of determining gene expression of Individual TCR versus subsets of TCR encompass different ingredients and endpoints,

b. Methods of identifying an antigen responsive T cell within an individual versus between different individuals encompass different method steps, samples and different endpoints,

c Methods of identifying an antigen-responsive T cell wherein the subset of T cell receptors comprise distinct variable regions encompass different ingredients and different endpoints,

d. Methods of treating a patient with an antigen mediated disease wherein the method comprises) T cell vaccination, B) anti-TCR antibody treatment or C)peptide immunization encompass different ingredients and method steps.

5. Applicant is required, in response to this action, to elect a specific species to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

6. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. The following claim(s) are generic: claims 1, 18-20.

8. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner
Group 1640
April 23, 2001

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644